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10/662,981

09/15/2003

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/662,981

Applicant(s)

SMITH ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 16-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/02; 3/04; 3/06; 2/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, Claims 1-15, in the reply filed on 2/9/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 16-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/9/2007.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 3/28/2000 and 9/17/2002. It is noted, however, that applicant has not filed a certified copy of the Australian applications as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 12/22/2003; 3/25/2004; 3/17/2006; and 2/20/2007 have been considered by the examiner and made of record.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 6, 7, 10-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Harm et al.(US 4,650,766).

With respect to claim 1, the reference of Harm et al. discloses a perfusion incubation device that includes a medium supply (20); at least one well assembly (92) having an upper portion (93) and a lower portion (89); and a peristaltic pump (36); where each well assembly (92) includes a medium inlet (96,98) and a medium outlet (102,104) and each medium outlet (102,104) is positioned above the medium inlet (96, 98) and the medium inlet (96,98) is connected to the medium supply (20) via the peristaltic pump (36) (See Figures 1 and 7).

With respect to claim 6, each well (92) has a stepped side wall defining an upper chamber and smaller diameter lower chamber (See the shape of element (91), Figure 7).

With respect to claim 7, lid (93) extends partially into the upper chamber (See Figure 7).

With respect to claim 10, the pump (36) is structurally capable of providing the recited flow rate.

With respect to claim 11, the device includes medium conditioning unit (16) that regulates the temperature and pH of the medium.

With respect to claim 12, the temperature regulator (16,40) is structurally capable of providing the intended heating recited in claim 12.

With respect to claim 13, the conditioning unit (16) includes gas permeable tubes (34a) for allowing gas to diffuse into the medium.

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With respect to claim 15, the structure of the conditioning unit (16) includes the use of a silicone tube and jacket for supplying a gas (See Figure 2 and column 5, lines 23-33).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 2, 3, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harm et al.(US 4,650,766) in view of Minuth (US 5,665,599).

The reference of Harm et al. has been discussed above.

Claims 2, 3, 8 and 9 differ by reciting that the culture well is constructed and/or combined with a microscope observation device.

The reference of Minuth discloses that it is conventional in the culture art to provide a culture well that is perfused with culture medium in combination with a microscope device and to make the culture well components out of transparent materials (See Figure 2 and related text).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art that the time the invention was made to construct the culture chamber of the primary reference such that it can be used with a microscope observation system for the known and expected result of allowing the contents of the culture chamber to be observed during the culture process.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harm et al.(US 4,650,766) in view of Armstrong et al. (GB 2 268 187).

The reference of Harm et al. has been discussed above.

While the reference of Harm et al. discloses the use of a gas permeable medium tube to supply gas to the culture medium, claim 14 differs by reciting that the culture chamber is made of a gas permeable material.

The reference of Armstrong et al. discloses that it is conventional in the art to provide a culture chamber of a gas permeable material (See page 2).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the culture chamber the primary reference of a gas permeable material for the known and expected result of "greatly" improving the diffusion of oxygen to the cells as suggested by the reference of Armstrong et al.

12. Claims 1-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al.(US 6,627,435 or WO 01/72954) in view of Harm et al.(US 4,650,766).

The references of Chan et al. disclose a perfusion incubator (See Figure 1) that includes a medium supply (5); at least one well assembly (7) having an upper portion (23) and lower portion (24); and a peristaltic pump (4); wherein each well assembly (7) includes a medium inlet (26) and a medium outlet (27), each medium outlet (27) positioned above the medium inlet (26) (See Figure 3).

Claim 1 differs by reciting that the medium inlet is connected to the medium supply via the peristaltic pump while the references of Chan et al. disclose that the medium outlet is connected to the peristaltic pump (See Figure 1).

The reference of Harm et al. discloses that when perfusing a culture chamber (92) it is known in the art to connected the medium inlet (96) to the medium supply (20) via a peristaltic pump (36).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to connect the medium inlet of the device of the primary references of Chan et al. to the medium supply via a peristaltic pump

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for the known and expected results of providing an alternative means recognized in the art for achieving the same result, pumping medium through the culture chamber.

With respect to claims 2 and 3, the references of Chan et al. disclose light (13) and microscope (15).

With respect to claims 4-6, the references of Chan et al. disclose the well configuration required of claims 4-6 (See Figure 3).

With respect to claims 7-9, the references of Chan et al. disclose transparent lid (37) and well chamber (7).

With respect to claim 10, the pump (4) is structurally capable providing the flow required of claim 10.

With respect to the medium regulation of claims 11-13, the references of Chan et al. disclose regulation devices (1 and 2).

With respect to claim 15, the reference of Harm et al. discloses that the use of a gas permeable tube (34a) is conventional in the art for allowing a gas to diffuse into the culture medium prior to introduction into the culture chamber.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a gas control system as disclosed by the reference of Harm et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al.(US 6,627,435 or WO 01/72954) in view of Harm et al.(US 4,650,766) taken further in view of Armstrong et al. (GB 2 268 187).



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The combination of the references of Chan et al. and Harm et al. has been discussed above.

While the modified primary reference the use of a gas permeable medium tube to supply gas to the culture medium, claim 14 differs by reciting that the culture chamber is made of a gas permeable material.

The reference of Armstrong et al. discloses that it is conventional in the art to provide a culture chamber of a gas permeable material (See page 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the culture chamber the modified primary reference of a gas permeable material for the known and expected result of "greatly" improving the diffusion of oxygen to the cells as suggested by the reference of Armstrong et al.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-13 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 16 of U.S. Patent No. 6,627,435 in view of Harm et al.(US 4,650,766).

Claims 1-11 and 16 of U.S. Patent 6,627,435 encompass a perfusion incubator that is substantially the same as that instantly claimed in claims 1-13 and 15.

The claims differ by reciting that the medium inlet is connected to the medium supply via the peristaltic pump while the claims of U.S. '435 recite that the medium outlet is connected to the peristaltic pump.

The reference of Harm et al. discloses that when perfusing a culture chamber (92) it is known in the art to connected the medium inlet (96) to the medium supply (20) via a peristaltic pump (36).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to connect the medium inlet of the device of the primary references of Chan et al. to the medium supply via a peristaltic pump for the known and expected results of providing an alternative means recognized in the art for achieving the same result, pumping medium through the culture chamber.

16. Claim 14 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 16 of U.S. Patent No. 6,627,435 in view of Harm et al.(US 4,650,766) taken further in view of Armstrong et al. (GB 2 268 187).

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The combination of claims 1-11 and 16 of U.S. Patent No. '435 and Harm et al. has been discussed above.

While the modified claims of U.S. Patent '435 encompass the use of a gas permeable medium tube to supply gas to the culture medium, claim 14 differs by reciting that the culture chamber is made of a gas permeable material.

The reference of Armstrong et al. discloses that it is conventional in the art to provide a culture chamber of a gas permeable material (See page 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the culture chamber the modified patented claims of a gas permeable material for the known and expected result of "greatly" improving the diffusion of oxygen to the cells as suggested by the reference of Armstrong et al.

### ***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB